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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
GALVEZ, JAMES JASON	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,653	ESCARY, JEAN-LOUIS	
	Examiner	Art Unit	
	J. Jason Galvez	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-8, 23 and 42, drawn to polynucleotides comprising the single nucleotide polymorphism (SNP) wherein cytosine is at position 771 of SEQ ID NO: 1, vectors, host cells and therapeutic agents comprising SNPs, vectors or host cells, classified in class 435, subclass 69.1/320.1/325, class 536, subclass 23.5 and class 514, subclass 44.
2. Claims 9-17 and 23, drawn to polynucleotides comprising the single nucleotide polymorphism (SNP) wherein adenine is at position 808 of SEQ ID NO: 1, vectors and host cells, classified in class 435, subclass 69.1/320.1/325, and class 536, subclass 23.5.
3. Claims 18 and 23, drawn polynucleotides comprising the single nucleotide polymorphism (SNP) wherein the result is the point mutation G45R of SEQ ID NO: 2, vectors and host cells, classified in class 435, subclass 69.1/320.1/325, and class 536, subclass 23.5.
4. Claims 19- 23, drawn to polynucleotides encoding SEQ ID NO: 3, vectors and host cells, classified in class 435, subclass 69.1/320.1/325, and class 536, subclass 23.5.

5. Claims 24-26 and 43, drawn to methods of genotyping/diagnosing disease based on the SNP at position 771 of SEQ ID NO: 1, classified in class 435, subclass 6.

6. Claims 24-26 and 44, drawn to methods of genotyping/diagnosing disease based on the SNP at position 808 of SEQ ID NO: 1, classified in class 435, subclass 6.

7. Claims 27, 28 and 42, drawn to polypeptides comprising SEQ ID NO: 2 or polypeptides comprising the point mutation G45R of SEQ ID NO: 2 and compositions comprising polypeptides comprising the point mutation G45R of SEQ ID NO: 2, classified in class 530, subclass 350.

8. Claims 29-32, drawn to polypeptides comprising SEQ ID NO: 3, classified in class 530, subclass 350.

9. Claim 33, drawn to antibodies directed to SEQ ID NO: 2 or polypeptides comprising the point mutation G45R of SEQ ID NO: 2, classified in class 530, subclass 387.1.

10. Claim 33, drawn to antibodies directed to SEQ ID NO: 3, classified in class 530, subclass 387.1.

11. Claims 34, 35, 38 and 39, drawn to methods of treatment by administering antibodies directed to SEQ ID NO: 2 or polypeptides comprising the point mutation G45R of SEQ ID NO: 2, classified in class 514, subclass 2.

12. Claims 34, 35, 38 and 39, drawn to methods of treatment by administering antibodies directed to SEQ ID NO: 3, classified in class 514, subclass 2.

13. Claims 36 and 37, drawn to methods of treatment by administering polypeptides SEQ ID NO: 2 or polypeptides comprising the point mutation G45R of SEQ ID NO: 2, classified in class 514, subclass 2.

14. Claims 36 and 37, drawn to methods of treatment by administering polypeptides of SEQ ID NO: 3, classified in class 514, subclass 2.

15. Claim 40, drawn to methods of identifying compounds with substantially the same activity as polypeptides comprising the point mutation G45R of SEQ ID NO: 2, classified in class 435, subclass 7.1.

16. Claim 41, drawn to methods of identifying compounds with substantially the same activity as polypeptides comprising SEQ ID NO: 3, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose the polynucleotides of inventions 1-4 as capable of use together. Furthermore, the inventions represent different molecules that have different sequences and different effects that require unique searches. The searches for the inventions are not coextensive. Each sequence constitutes a separate and distinct search of the prior. Therefore, searching the inventions together would impose a serious search burden on the Examiner and USPTO resources.

Inventions 1 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention 1 can be used in a materially different process, such as the production of recombinant polypeptides.

In addition, the inventions 1 and 5 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the claimed products and methods genotyping using the claimed products is not coextensive. Inventions 1 and 5 are separate and distinct by way of their different classifications and divergent subject matter. Therefore, searching the inventions together would impose a serious burden on the Examiner and USPTO resources.

Inventions 1/3/4 and 6 are unrelated because the products of inventions 1, 3 and 4 are not used or otherwise involved in the methods of invention 6.

Inventions 1-4 (polynucleotides) and 7-8 (polypeptides) are distinct from one another because polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules than polypeptides, which are composed of amino acids; any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, polypeptides can be made by another materially different process than from

recombinant polynucleotide expression, such as chemical synthesis or isolation/purification from natural sources.

Furthermore, searching inventions 1-4 and 7-8 together would impose a serious search burden. In the instant case, the search of the polynucleotides and polypeptides are not coextensive. Inventions 1-4 and 7-8 have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched separately in appropriate databases. There is also a search burden in regards to non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides that would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers that expressed no knowledge of a polypeptide but spoke of its corresponding gene.

Inventions 1-4 (polynucleotides) and 9-10 (antibodies) are distinct from another because polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules than antibodies, which are composed of amino acids consisting of 2 light and 2 heavy chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs).

Furthermore, the inventions directed to polynucleotides and antibodies have a separate status in the art as shown by their different classifications. For the reasons given above, searching inventions 1-4 and 9-10 together would impose a serious search

burden on the Examiner and USPTO resources since a search of the polynucleotides would not be used to determine the patentability of the antibodies, and vice-versa.

Inventions 1-4 and 11-16 are unrelated because the products of inventions 1-4 are not used or otherwise involved in the methods of any of inventions 11-16.

Inventions 2-4 and 5 are unrelated because the products of inventions 2-4 are not used or otherwise involved in the methods of invention 5.

Inventions 2 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention 2 can be used in a materially different process, such as the production of recombinant polypeptides.

In addition, the inventions 2 and 6 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the claimed products and methods genotyping using the claimed products is not coextensive. Inventions 2 and 6 are separate and distinct by way of their different classifications and divergent subject matter. Therefore, searching the inventions together would impose a serious burden on the Examiner and USPTO resources.

Inventions 5-6 and 7-10 are unrelated because the methods of inventions 5-6 do not use or otherwise involve the products of inventions 7-10.

Inventions 5-6 and 11-16 are each unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Inventions 5-6 and 11-16 are each directed towards different methods that have different modes of operation, different functions, different starting materials, different effects, and/or different outcome measures.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or separate search requirement based on particular aspects of the inventions, e.g. inventions using different starting materials or inventions having different effects, it would impose a serious burden on the Examiner and USPTO resources to search the inventions together.

Inventions 7-8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose the polypeptides of inventions 7-8 as capable of use together. Furthermore, the inventions represent different molecules that have different sequences and different effects requiring unique searches. The searches for the inventions are not coextensive. Each sequence constitutes a separate and distinct search of the prior. Therefore, searching the inventions together would impose a serious search burden on the Examiner and USPTO resources.

Inventions 7-8 and 9-10 are distinct from one another because the polypeptides of inventions 7-8 and the antibodies of invention 9-10 are directed to distinct chemical entities. While the inventions 7-8 and 9-10 are polypeptides, in this instance the polypeptides of inventions 7-8 are most likely a single chain molecule, whereas the polypeptides of inventions 9-10 encompass antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptides of inventions 7-8 and the antibodies of the inventions 9-10 are structurally distinct molecules; any relationship between a polypeptide and an antibody is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions 7-8 and 9-10 would impose an undue search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies. In addition, the technical literature search for polypeptides and antibodies may not be coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequence of, their binding target.

Inventions 7 and 11-12/14/16 are unrelated because the products of invention 7 are not used or otherwise involved the methods of inventions 11, 12, 14 or 16.

Inventions 7 and 13/15 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention 7 can be used in a materially different process, such as the production of monoclonal antibodies.

In addition, the inventions 7 and 13/15 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the claimed products and methods of using the claimed products is not coextensive. Inventions 7 and 13/15 are separate and distinct by way of their different classifications and divergent subject matter. Therefore, searching the inventions together would impose a serious burden on the Examiner and USPTO resources.

Inventions 8 and 11-12/13/15 are unrelated because the products of invention 8 are not used or otherwise involved the methods of inventions 11, 12, 13 or 15.

Inventions 8 and 14/16 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of

invention 8 can be used in a materially different process, such as the production of monoclonal antibodies.

In addition, the inventions 8 and 14/16 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the claimed products and methods of using the claimed products is not coextensive. Inventions 8 and 14/16 are separate and distinct by way of their different classifications and divergent subject matter. Therefore, searching the inventions together would impose a serious burden on the Examiner and USPTO resources.

Inventions 9-10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose the antibodies of inventions 9-10 as capable of use together. Furthermore, the inventions represent different molecules that have different sequences and different effects requiring unique searches. The searches for the inventions are not coextensive. Each sequence constitutes a separate and distinct search of the prior. Therefore, searching the inventions together would impose a serious search burden on the Examiner and USPTO resources.

Inventions 9 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of

invention 9 can be used in a materially different process, such as immunocytochemical staining of tissue.

In addition, the inventions 9 and 11 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the claimed products and methods of using the claimed products is not coextensive. Inventions 9 and 11 are separate and distinct by way of their different classifications and divergent subject matter. Therefore, searching the inventions together would impose a serious burden on the Examiner and USPTO resources.

Inventions 9 and 12-16 are unrelated because the products of invention 8 are not used or otherwise involved the methods of any of inventions 12-16.

Inventions 10 and 11/13-16 are unrelated because the products of invention 10 are not used or otherwise involved the methods of inventions 11, or 13-16.

Inventions 10 and 12 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention 10 can be used in a materially different process, such as immunocytochemical staining of tissue.

In addition, the inventions 10 and 12 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the

claimed products and methods of using the claimed products is not coextensive. Inventions 10 and 12 are separate and distinct by way of their different classifications and divergent subject matter. Therefore, searching the inventions together would impose a serious burden on the Examiner and USPTO resources.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejections or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections under 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D**. whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to

5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JJG
6/16/2005

Bridget E. Bunner
patent examiner